UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

August 26, 2013

MEMORANDUM

Subject: Efficacy Review for Sanosil HaloMist; EPA File Symbol 84526-A; DP Barcode: D409339.

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Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Sanosil International, LLC
91 Lukens Drive, Suite A
New Castle, DE 19720

Formulation from the Label:

Active Ingredient	% by wt.
Hydrogen Peroxide	5.00 %
Silver	0.01 %
Inert Ingredients:	94.99 %
Total	100.00 %

I. BACKGROUND

The product, Sanosil HaloMist (EPA File Symbol 84526-A) is a new product. The applicant has requested to register the product as a disinfectant (bacteria and *Clostridium difficile* spores) for use on dry pre-cleaned hard, non-porous surfaces in health-care facilities, when applied by fogging. Sanosil HaloMist is a disinfectant solution that will be used only with Sanosil Halo Fogger. The registrant claims that Sanosil HaloMist is identical in composition and similar in use to Sanosil S010 (EPA Reg. No. 88494-1). The registrant intends to rely on the laboratory studies previously conducted with Sanosil S010 and submitted to the Agency. These studies demonstrated efficacy of Sanosil S010 as a hospital disinfectant. Field studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated January 10, 2013), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-35 (Data Matrix), four studies (MRID Nos. 490368-01 through 490368-04), Statements of No Data Confidentiality Claims for all four studies, Sanosil Halo Fogger User Manual, and the proposed label.

II. USE DIRECTIONS

The product, Sanosil HaloMist, is designed for use with the Sanosil Halo Fogger. Upon addition of Sanosil HaloMist to the Sanosil Halo Fogger, a dry, disinfecting mist is produced. The product is for use in sealed, enclosed spaces and rooms in health-care facilities. The proposed label did not include any directions regarding the use and preparation of the product as a fogger.

User Manual

For use in rooms 1100 ft^3 up to 3700 ft.^{3}

Disinfectant Application Process

Only Sanosil HaloMist disinfectant should be used in the Halo Fogger. Sanosil HaloMist is applied at a rate of approximately 1.0 oz per minute for a minimum of 10 minutes and maximum of 60 minutes depending upon the room size. ~~Room sizes larger than 10,500 ft^3 may require validation with multiple fogger systems. Fogging of rooms smaller than 400 ft^3 is not recommended~~ 1100 ft^3 prohibited. with this process.

The Halo Fogger uses air as a carrier to deliver a dry mist (suspension of small liquid droplets in the air) of Sanosil HaloMist to exposed surfaces inside a sealed room for a selected time based on the size of the room. The Sanosil HaloMist disinfectant is continuously fogged for the required dispensing time to maintain the desired concentration of Sanosil HaloMist. The Halo Fogger will automatically stop fogging at the selected time. Sanosil HaloMist Disinfectant decomposes into water and oxygen.

Dehumidification

The Halo Fogger and Sanosil HaloMist disinfection process can consist of 1, 2, or 3 phases depending upon application. The Dehumidification phase is optional if the room to be disinfected is below 50% relative humidity. Room air is first circulated in the sealed treatment room by the dehumidifier to reduce humidity to a predetermined level in the 30-50% relative humidity (RH)

range. This permits the target Dry Mist Hydrogen Peroxide (DMHP) concentration to be maintained below condensation levels during the disinfection phase. The time to reach the targeted dehumidification level increases with the volume of the room, and is dependent on environmental conditions.

Disinfection

Sanosil HaloMist disinfectant is continuously fogged for a selected time to obtain the target DMHP concentration over a pre-established period of time for the volume of the enclosed area.

Post-Dehumidification

The Post Dehumidification phase is optional if accelerated room re-entry is not necessary. The dehumidifier will speed the reduction of the DMHP concentration within the room to a 1 ppm level prior to re-entry into the room by trained applicators. Treated rooms may not be released for general public use until one hour after a 1 ppm level of DMHP is achieved in the room as indicated by anyone to enter

Disinfection Management Plan

GENERAL—Employees of the site to be disinfected should develop a site specific Disinfection Management Plan (DMP) for each room to be fogged with Sanosil HaloMist. The user is responsible for all tasks of the disinfection process unless noted in the DMP and must be on site for the entire disinfection treatment process. The DMP must address a full characterization of the site, and include appropriate monitoring and notification requirements, consistent with, but not limited to, the following:

- Inspect the structure and or area to determine its suitability for disinfection (size, non-porous surfaces, pre-cleaned)
- When sealing is required, seal leaks and monitor any occupied adjacent rooms and/or buildings to ensure safety.
- Prior to each disinfection, review any existing DMP, MSDS, Equipment Manuals and other relevant safety procedures with company officials and appropriate employees.
- Consult with company officials in the development of procedures and appropriate safety measures for nearby workers who will be in and around the area during application and aeration.
- Consult with company officials to develop an appropriate monitoring plan that will confirm that nearby workers and bystanders are not exposed to levels above the allowed limits during application. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.
- Confirm the placement of placards to secure entrance into any area under disinfection.
- Confirm the required safety equipment is in place and the necessary manpower is available to complete disinfection.

These factors must be considered in putting a DMP together. It is important to note that some plans will be more comprehensive than others. All plans should reflect the experience and expertise of the applicator and circumstances at and around the structure and/or area. In addition to the plan, the user mus read the entire label and equipment manuals and follow all directions carefully. If the user has any questions about the development of a DMP, contact Sanosil International or authorized distributor for further assistance.

Personnel

Training and Certification of Applicators

- Prior to use, applicators must be adequately trained and certified by Sanosil International or its authorized distributor or reseller on the hazards and label directions for Sanosil HaloMist, on the use and operation of the DMHP application equipment, Sanosil HaloMist monitoring procedures and when appropriate, validation procedures.
- Confirm in writing that all personnel in and around the area to be fogged have been notified prior to application of the disinfectant. Consider using a checklist that each employee initials indicating that they have been notified.
- Instruct all disinfection personnel about the hazards that may be encountered; and about the selection of PPE, including detection equipment.
- Confirm that all personnel are aware of and know how to proceed in case of an emergency situation.
- Instruct all personnel on how to report any accident or incidents related to disinfectant exposure.
- Establish a meeting area for all personnel in case of emergency
- Confirm that all applicators have been trained in the use of Sanosil HaloMist disinfectant and are in good standing including the required refresher training.
- Develop a Worker Health and Safety Plan as required by OSHA for applicators. The owner and operators of the facility being treated should have a Worker Health and Safety Plan as required by OSHA developed for their employees located within close proximity of the application process.

Monitoring

A. Perimeter Safety
    - Monitoring of Sanosil HaloMist concentration must be conducted immediately adjacent to the fogged space to prevent excessive exposure and to determine where exposure may occur. Documenting where monitoring will occur.
    - Keep a log of manual of monitoring records for each disinfection site. This log must at a minimum contain the timing, number of readings taken and level of concentration found in each location.
    - When monitoring for leaks, document that there is no DMHP present above the 1.0 ppm level. Subsequent leak monitoring is not routinely required. However spot checks must be made, especially if conditions significantly change.
    - Monitoring must be conducted during aeration and corrective action taken if H_2O_2 levels exceed the allowed levels in an area where bystanders or nearby residents may be exposed.

Ensure that the adjacent areas where levels have exceeded 1 ppm are evacuated by general personnel and that proper respiratory protection is utilized by applicators that enter the area. Continue monitoring the area until levels are below 1 ppm DMHP. The treated room and adjacent areas must remain unoccupied until one hour after DMHP levels are at or below 1ppm.

B. Efficacy
    - Proper placement of Chemical Indicators (CIs) in all areas of the room to assure consistent delivery.

- Document Sanosil Halo Fogger run times, temperature, room humidity, and CI color change.

Sealing Procedures

- Sealing must be adequate to prevent any leaks. Care should be taken to ensure that sealing materials remain intact until the disinfection is complete. Verify effectiveness of the sealing process by conducting a smoke stick test to ensure there are no leaks where openings have been sealed in the room.
- If the structure and/or area have/has been fogged before, review the previous DMP information.
- Make sure that construction or remodeling has not changed the building in a manner that will affect the disinfection process.
- Warning placards must be placed on every possible entrance to the disinfection site.

Application Procedures and Disinfection Period

- Plan carefully and apply disinfectant in accordance with the label requirements.
- When entering into the area under disinfection always work with two or more people under the direct supervision of a trained applicator wearing appropriate PPE.
- Provide watchmen when a disinfection site cannot otherwise be made secure from entry by unauthorized persons.
- Follow Sanosil Halo Fogger Use Instructions.

Post-Application Operations

- Provide watchmen when you cannot secure the disinfection site from entry by unauthorized persons during the aeration process.
- Ventilate and aerate in accordance with structural limitations.
- Turn on ventilating or aerating fans where appropriate.
- Use a suitable DMHP detector before reentry to determine disinfectant concentration (example: Dragger PAC III or ATI PortaSens II).
- Keep written records of monitoring to document completion of aeration.
- Remove warning placards when aeration is complete.
- Inform business clients that employees or other persons may return to work or otherwise be allowed to re-enter the aerated structure.

Criteria for Successful Disinfection

All Cis that are properly recovered and evaluated exhibit a visible color change following exposure to DMHP.

Sanosil Halo Fogger Use Instructions

Room Preparation

- Remove porous curtains, fabrics, and associated porous items from room, including: bed linens, waste products and visible dirt.
- Cleaning: remove gross filth and visible soil prior to application. Wash soiled surfaces with a compatible detergent using a cloth, sponge, wipe or appropriate cleaning device to ensure visible soils are removed. Rinse with potable water and allow to air dry. All the surfaces in the treatment area must be completely dry to the touch or visibly dry prior to DMHP application.

IMPORTANT—The Sanosil Halo Fogger does not replace the requirement for manual room cleaning. You must follow facility's cleaning procedure before using the Sanosil Halo Fogger.

Room Set Up

- Sealing—Seal the treatment room adequately to assure that DMHP levels outside the room are kept at acceptable levels.
- Close and seal windows and doors. Sealing technique can vary, but most often includes polyethylene sheeting and adhesive tape. Verify effectiveness of the sealing process by conducting an air draft potential analysis using a smoke stick to ensure there are not leaks where openings have been sealed in the room.
- If possible, turn off all ventilation systems including HVAC and seal any supply or return vents and duct work and cover any smoke detectors.
- Open internal doors, cupboards, and drawers of room furniture unless specifically directed to leave them closed (as in the operating room).
- Remove mattresses from beds and tilt them on their sides.
- Monitor areas immediately adjacent to the fogged apace to ensure levels are below TWA for DHMP.
- If possible, modify ambient conditions in the room to meet the following recommended parameters: Temperature: 20±4°C (68 ±7°F); Relative humidity: between 30%-70%
- Assure all personnel have vacated the treatment room prior to DMHP application. Remove all plants, animals, beverage and food.
- Applicators must no reenter the treated room until exposure levels of DMHP are at or below one ppm. Do not release the treated room to the general public until 1 hour after a level of one ppm Sanosil HaloMist is achieved in the room.
- Placard Placement in Treatment Room: The applicator must placard or post all entrances to the .... And designated buffer zones with signs in English bearing:
    - The signal word "CAUTION/PRECAUCION" in red;
    - "Area under treatment, DO NOT ENTERINO/ENTER"
    - The statement "This sign may only be removed after treatment of enclosed area, one hour after DMHP levels are less than or equal to one ppm";
    - Identification of Sanosil HaloMist as hazard associated with the treatment process;
    - Contact information for the applicator

  All entrances to the treatment room must be placarded. Placards must be placed in advance of the treatment in order to keep unauthorized persons from entering the treated room. Placards can be removed one hour after the treatment room contains concentrations of DMHP are at or below 1 ppm.

Treatment Procedure Protocol

- Position the Halo Fogger in a corner of the room approximately one foot away from the wall, pointing the nozzle towards the entrance of the room. Choose a corner farthest away from vents, ductwork and door. IMPORTANT—Dispensing airflow path from the Halo Fogger must remain unobstructed during the entire treatment procedure.
- Measure the length, width and height of the room. Round up to the nearest cubic foot and cubic meter. These measurements will determine the final room size and recommended run-time of the Halo Fogger.
- Plug the Halo Fogger into a standard, grounded electrical wall outlet. When the power connection has been made, the green status indicator light on top of the device will illuminate.

- Using the chart below (also found on the rear of the device or in the Halo User Manual) determine the Fogging Time based on the room size (cu ft or m^3) from Step 2 above.
- Turn the timer dial on the top of the Halo to the number of minutes specified for your room size. Do not set the time for longer than the suggested time. Excessive fogging can cause condensation, which may reduce effectiveness and may activate fire alarm systems.
- Check the fluid level indicator lights to see level of Sanosil Disinfectant in the Halo. It is recommended the unit reservoir be topped off before proceeding with the treatment process.
- Press and hold the Halo Start button for seconds. The green status indicator light will begin to flash red, indicating that you have 30 seconds to leave the room before the Halo device begins to operate.
- Close the door to the room after you have exited. Post a sign on the door indicating that the room should not be entered during treatment process. Note time treatment process was started on room sign.
- After 30 seconds, the status indicator light will turn solid red and the Halo will begin to dispense Sanosil Disinfectant into the room. It is likely that you will hear the Halo running through the door.
- When the Halo has finished dispensing the room will be full of atomized Sanosil Disinfectant mist. The status indicator will remain illuminated red. Do not enter the room at this time.
- The treated room must remain unoccupied until the minimum room reentry wait time has expired and hydrogen peroxide concentration level (ppm) has been checked. 110 minutes is the minimum wait time for re-entry; length of wait time increases with room size. Whenever possible, delay reentry and allow treated room to remain unoccupied overnight for safety and maximum efficacy. Hydrogen peroxide concentration levels must be at or below one ppm for safe room re-entry. Once safe levels are determined to be at or below one ppm, it is recommended that all doors and HVAC vents be opened and HVAC system be restarted to allow increased ventilation and airflow circulation in the room. Uncover smoke detectors.
- Upon expiration of room reentry wait time, to assure occupational health levels are not exceeded, using a handheld hydrogen peroxide detector, verify safe hydrogen peroxide concentration level is at or below one ppm. If level is not at or below one ppm, wait an additional 10 minutes and re-check. Continue to check until safe health exposure level is at or below one ppm. Treated room can be re-occupied one hour after hydrogen peroxide concentration level is determined to be at or below 1 ppm.
- When treatment is complete, unplug the Halo Fogger from the power source.

Disinfecting for High Humidity Environments and Applications Requiring Accelerated Room Re-entry—Special Instructions

Prepare the room as outlined in Room Preparation and Room Set-Up—then

- Room humidity level of 30% - 50% or less is recommended before starting the treatment process. Some rooms may have higher humidity level which can extend the room reentry time. Position the dehumidifier next to Hal Fogger. Verify that the dehumidifier's reservoir is empty or empty reservoir prior to use.
- Plug dehumidifier into the correct location on the Sanosil Power Module, and then plug the power module into a standard, grounded electrical wall outlet.

- Turn on dehumidifier; set fan to highest speed setting. Check humidity level with humidity sensor; if humidity level is above 50%, let dehumidifier run until the humidity level is reduced to recommended level.
- Plug the Sanosil Halo into the correct location on the Sanosil Power Module. When the power connection has been made, the green status indicator light on top of the device will illuminate.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

To obtain claims for fogging, a two-tiered approach must be conducted to include both a laboratory test and a field test, with the same performance standard. The evaluations must include a complete set of data on three batches of product at no more than the LCL.

The field test must be conducted under a field use scenario such as a room or large chamber (dimensions should be proposed prior to initiation of the test), to achieve the proposed performance standard. Prior to data generation, the registrant must provide a comprehensive discussion of the product's distribution and deposition for each unit after a typical application period (i.e. a typical application run provides "x" amount of product over volume). This information is required to adequately determine the number and distribution of carriers necessary to perform the efficacy test. The method selected for conducting the laboratory test should be used to process the carriers in the field test.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments by fogging or misting must be substantiated by data derived using Agency approved protocols. The tests require that at least sixty carriers must be tested with each of 3 samples, representing 3 different batches at no more than the LCL concentration, in 3 cycles, against *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen), [120 carriers per sample; a total of 360 carriers]. To support products labeled as "disinfectants", killing on 59 out of every 60 carriers set is required to provide effectiveness at the 95% confidence level. Volume of enclosure, treatment effectiveness height, mist/fog and delivery equipment characteristics must be specified.

IV. BRIEF DESCRIPTION OF THE DATA

Note: Certificates of Analysis of the tested product lots 12I001, 1109B, 1109C, 1206D, and 1211D were submitted by the registrant and were each found to contain respectively, 4.76%, 4.78%, 4.77%, 4.75%, and 4.74% Hydrogen Peroxide, and 0.000849%, 0.00981%, 0.01024%, 0.00988%, and 0.00970% Silver.

1. MRID 490368-04 "Characterization Assays of Sanosil S010" by David J. Sinning. Study conducted at Case Laboratories, Inc. Study completion date – December 17, 2012. Project Number 3700-18.

This study was conducted to determine the concentration of active ingredients in five lots (12I001, 1109B, 1109C, 1206D, and 1211D) of Sanosil HaloMist (Sanosil S010) and were found to contain, respectively, 4.76%, 4.78%, 4.77%, 4.75%, and 4.74% Hydrogen Peroxide, and 0.000849%, 0.00981%, 0.01024%, 0.00988%, and 0.00970% Silver.

2. MRID 490368-01 "Efficacy of a Disinfectant Applied to a Room via a Fogger or Misting Device" against *Pseudomonas aeruginosa* (ATCC 15442) and *Staphylococcus aureus* (ATCC 6538); for Sanosil S010, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – December 12, 2012. Project Number A14153.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 1109C, 1206D, and 12I001) of the product, Sanosil HaloMist (Sanosil S010), were tested using ATS Protocol SAN01101311.RDT (copy provided). One of the lots tested (Lot No. 1109C) was at least 60 days old at the time of testing. The product was received ready-to-use. Sixty two (62) glass slide carriers were tested per cycle, organism, and product lot in a sealed (including HVAC vents) 3663.7 $feet^3$ or 104 m^3 room volume. Treatment cycles were 167-172 minutes (~3hours). Standard humidifier/dehumidifier was used to reach the environmental conditions of 35-45% relative humidity levels. An aliquot of 0.01 ml of a 48-54 hour old broth culture of the test organism was transferred onto each carrier. The inoculum was spread uniformly over the test surface of each carrier. The carriers were dried for 30 minutes at 35-37°C with 52.7-55.9% relative humidity. Test carriers and chemical indicators (CIs) were positioned within the room but **not higher than 8 feet**. Internal (post-treatment) controls were placed within a sealed container (an anaerobe jar with no gas pack) and held in the room during the test substance application. The application was 1.0 oz per minute in the test room for 22-24 minutes fogging followed by 143-150 minutes room aeration at room temperature (22.4-23.6°C). Following treatment, carriers were transferred individually into 20 ml of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80 and 0.01% Catalase to neutralize. CIs were observed for color change and the results were recorded. All subcultures were incubated for 48±4 hours at 35-37°C (and stored at 2-8°C for one day) then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and dried carrier pre and post treatments counts. The reported average colony forming units per post-treatment carrier, for each test microorganism, are as follows: ***Staphylococcus aureus* 9.567 x 10^5, *Pseudomonas aeruginosa* 1.0 x 10^6**.

Note: Protocol amendments reported in this study were reviewed.
Note: The fogging device was not functioning correctly when using the lot 12I001 for *Staphylococcus aureus* (ATCC 6538) because the unit was not properly maintained. This resulted in a failure; therefore, a retest was conducted with a functional unit.

3. MRID 490368-02 "Efficacy of a Disinfectant Applied to a Room via a Fogger or Misting Device" against *Staphylococcus aureus* (ATCC 6538); for Sanosil S010, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – January 3, 2013. Project Number A14436.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot No. 1211D) of the product, Sanosil HaloMist (Sanosil S010), was tested using ATS Protocol SAN01121312.RDT (copy provided). The lot tested was at least 60 days old at the time of testing. The product was received ready-to-use. Sixty two (62) glass slide carriers were tested per cycle in a sealed (including HVAC vents) 3663.7 $feet^3$ or 104 m^3 room volume. Treatment cycle was approximately 180 minutes (3 hours). Standard humidifier/dehumidifier was used to reach the environmental conditions of 25-35% relative humidity levels. An aliquot of 0.01 ml of a 48-54 hour old broth culture of the test organism was transferred onto each carrier. The inoculum was spread uniformly over the test surface of each carrier. The carriers were dried for 40 minutes at 35-37°C with 40% relative humidity. Test carriers and chemical indicators (CIs) were positioned within the room but **not higher than 8 feet**. Internal (post-treatment) controls

were placed within a sealed container (an anaerobe jar with no gas pack) and held in the room during the test substance application. The application was 1.0 oz per minute in the test room for 25 minutes fogging followed by 155 minutes room aeration at room temperature (21.4-22.1°C). Following treatment, carriers were transferred individually into 20 ml of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80 and 0.01% Catalase to neutralize. CIs were observed for color change and the results were recorded. All subcultures were incubated for 48±4 hours at 35-37°C then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and dried carrier pre and post treatments counts. The reported average colony forming units per post-treatment carrier, for the test microorganism is: ***Staphylococcus aureus* 1.29 x 10^6**.

4. MRID 490368-03 "Efficacy of a Disinfectant Applied to a Room via a Fogger or Misting Device" against *Clostridium difficile* - spore form (ATCC 43598); for Sanosil S010, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – December 11, 2012. Project Number A14152.

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598). Three lots (Lot Nos. 1109C, 1206D, and 12I001) of the product, Sanosil HaloMist (Sanosil S010), were tested using ATS Protocol SAN01101111.CUST (copy provided). One of the lots tested (Lot No. 1109C) was at least 60 days old at the time of testing. The product was received ready-to-use. Sixty two (62) brushed stainless steel disk carriers were tested per cycle and product lot in a sealed (including HVAC vents) 3663.7 $feet^3$ or 104 m^3 room volume. Treatment cycles were 165-172 minutes (~3hours). Standard humidifier/dehumidifier was used to reach the environmental conditions of 35-45% relative humidity levels. An aliquot of 0.01 ml of a 48-54 hour old broth culture of the test organism was transferred onto each carrier. The inoculum was spread uniformly over the test surface of each carrier. The carriers were dried for 30 minutes at 35-37°C with 52.7-55.9% relative humidity. Test carriers and chemical indicators (CIs) were positioned within the room but **not higher than 8 feet**. The application was 1.0 oz per minute in the test room for 22-24 minutes fogging followed by 143-150 minutes room aeration at room temperature (22.4-23.6°C). Following treatment, carriers were transferred individually into 10 ml of Letheen Broth with 0.07% Lecithin, 0.5% Tween 80 and 0.01% Catalase to neutralize; sonicated for 5 minutes; scraped; vortex mixed for approximately 45-60 seconds; then the entire content filtered. Carriers were rinsed 3 times with 10 ml of sterile saline filtered through same individual filters. Each filter was placed onto the surface of the recovery agar plate. CIs were observed for color change and the results were recorded. All subcultures plates were incubated anaerobically for 48±4 hours at 35-37°C (and stored at 2-8°C for one day) then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and dried carrier pre and post treatments counts. The reported average colony forming units per post-treatment carrier, for the test microorganism is: ***Clostridium difficile* 3.43 x 10^6**.

Note: Protocol amendments and deviations reported in this study were reviewed.

V. RESULTS

MRID # 490368-03	Results / 62 carriers				Average Dried Carrier Count (CFU/carrier)
		Lot 1109C	Lot 1206D	Lot 12I001	
Clostridium difficile (ATCC 43598)	Average Count	<1.07	<1	<1	3.43 x 10^6
	Percent Red	>99.9999%	>99.9999%	>99.9999%	
	Log_{10} Reduction	>6.58	>6.54	>6.44	

All chemical indicators were positive (change of color from white to blue/black)

MRID Number	Organism	No. Exhibiting Growth/Total No. Tested			Average Dried Carrier Count (CFU/carrier)	
		Lot 1109C	Lot 1206D	Lot 12I001	Pre-Treat	Post-Treat
490368-01	*Pseudomonas aeruginosa*	0/62	0/62	0/62	6.0×10^6	9.3×10^5
	Staphylococcus aureus	0/62	1/62	5/62	1.07×10^6	9.567×10^5
490368-02		Lot 1211D	-	-		
	Staphylococcus aureus	0/62	-	-	1.18×10^6	1.29×10^6

All chemical indicators were positive (change of color from white to blue/black)

VI. CONCLUSION

1. The submitted efficacy data (MRID Nos. 490368-01 thru 490368-04) **support** the use of undiluted Sanosil HaloMist fogged using only Sanosil Halo Fogger, as a disinfectant against against *Clostridium difficile* spores, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*, on **pre-cleaned** hard, non-porous surfaces **not higher than 8 feet**, in no more than **104 m^3 (3663.7 $feet^3$)** room. Fog must be applied at 1.0 oz per minute in the room for 22-24 minutes followed by 143-150 minutes room aeration at room temperature (22.4-23.6°C).

For re-testing with the over 60 day sample - Lot 1211D for Staphylococcus aureus, the fogging device was not functioning correctly because the unit was not properly maintained which resulted in a failure; therefore, a retest was conducted with a functional unit. Based on the registrants rationale (6/27/13 letter from Sanosil Int.), the results of this re-tested lot are allowed to support product registration.

VII. LABEL

1. It is not realistic that all non-porous surfaces be properly pre-cleaned before fogging. The product should be tested with a **3-part soil load**, or at least 5% organic soil load. Only visible filth would be removed then.

2. The proposed label claims **are acceptable** regarding the use of Sanosil HaloMist at full strength, by Fogging Application, using only Sanosil Halo Fogger, to disinfect **pre-cleaned** hard, non-porous surfaces at **not higher than 8 feet**, following a complete cycle (~3 hours), in a room **≤3663.7ft^3 (104 m^3)** against *Clostridium difficile* spores, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* at room temperature, as supported by the submitted efficacy data.

These claims are acceptable as supported by efficacy data provided by the applicant.

2. The applicant must make the following changes to the proposed label, as appropriate:

- On page 1, under "Direction for Use", add **8 feet** as the maximum effectiveness height

for pre-cleaned hard non-porous surfaces present in the treated room.

- On page 2, **remove** from the proposed label:
    - **"All-purpose"**
    - **"Fast"**
    - Brackets from **pre-cleaned, hard non-porous**; as the pre-cleaning step is not optional.
    - **"Inert bacteria"**

- On pages 3 and 4 of the proposed label, **add** "**pre-cleaned**" to all references of "**hard non-porous surfaces**".

- On page 3 of the proposed label, remove "**first**" because this product is not the first disinfectant by fogging to be registered by the Agency.

- On page 6 of the User Manual, under "Room Preparation", indicate that **all hard non-porous surfaces with visible or non-visible soils must be cleaned**.

- On page 7 of the User Manual, **specify** what is to be tilted to the side (Mattresses or bed frames). Mattresses are not supposed to be in the room during treatment.